Atty. Docket No. PR60419USw

IAP9 Rec'd PCT/PTO 01 FEB 2006

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE: Application of Neil Lee SPECTOR et al.

Serial No.: To be assigned

Art Unit: To be assigned

Filing Date: Concurrently herewith

Examiner: To be assigned

For: *Treatment of Cancers Expressing P95 ERBB2*

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Applicants request that the references identified on Form PTO-1449 appended hereto be considered by the Examiner and officially made of record in accordance with the provisions of 37 CFR 1.97

[X] Copies of the references listed on the attached form PTO-1449 as item nos. 5-20 are enclosed
[ ] Copies of the references were submitted in parent application Serial No. _____. (37 CFR 1.98(d))
[X] A copy of the International Search Report which issued on International Application No. _____PCT/US2004/024888_____ is submitted herewith. All of the publications cited in the International Search Report are listed on the attached form PTO-1449 as item no. 21 and Applicants understand that copies have been supplied to the U.S. Patent Office by the International Bureau.

A. [X] The Information Disclosure Statement submitted herewith is being filed within three months of the filing date of the above application or date of entry into the national stage of an international application or before the mailing date of a first Office action on the merits, whichever event occurs last. 37 CFR 1.97(b).

OR

[ ] **The Information Disclosure Statement submitted herewith is being filed before the mailing of a first office action after the filing of a Request For Continued Examination under 37 C.F.R. 1.114 (37 C.F.R. 1.97(b)(4)).**

B. [ ] The Information Disclosure Statement transmitted herewith is being filed **after** three months of the filing date of the above application or the date of entry into the national stage as set forth in § 1.491 of an international application or after the mailing date of the first Office Action on the merits, whichever event occurred last, but **before** the mailing date of either:
(1) a final action under § 1.113 or
(2) a notice of allowance under § 1.311,
whichever occurs first.

[ ] Applicant hereby certifies that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement.

[ ] Applicant elects the option to pay the fee set forth in 37 CFR 1.17(p) for submission of an Information Disclosure Statement under § 1.97(c) ($180.00).

C. [ ] The Information Disclosure Statement transmitted herewith is being filed **after** a final action under § 1.113, or a notice of allowance under § 1.311, whichever occurs first, but before the payment of the issue fee. Also enclosed is a copy of the International Search Report which Issued on International Publication No.

In accordance with the requirements of 37 CFR 1.97(d):

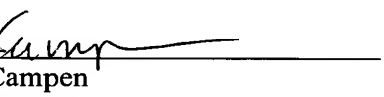
[ ] Applicant hereby certifies that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement. **[or]**

[ ] Applicant hereby certifies that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to my knowledge after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of this statement; and

[ ] The petition fee set forth in § 1.17(i)(1) ($180.00) is submitted herewith.

[X] Please charge any required fees to Deposit Account No.07-1392.
[ ] A duplicate copy of this paper is attached.

Respectfully Submitted,



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FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT	ATTORNEY DOCKET NO. PR60419USw	SERIAL NO. To be assigned
	APPLICANT Neil Lee SPECTOR et al.	
	FILING DATE Concurrently herewith	GROUP To be assigned

U.S. PATENT DOCUMENTS

Examiner Initials		Patent Number	Issue Date	Name	Class	Subclass	Filing Date If Appropriate
	1.	6,169,091	01/02/2001	COCKERILL et al.			
	2.	6,174,889	01/16/2001	COCKERILL et al.			
	3.	6,207,669	03/27/2001	COCKERILL et al.			
	4.	6,391,874	05/21/2002	COCKERILL et al.			

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FOREIGN PATENT DOCUMENTS

		Document Number	Publication Date	Country	Class	Subclass	Translation Yes | No
	5.	WO 99/35146	07/15/1999	PCT			X
	6.	WO 01/04111	01/18/2001	PCT			X
	7.	WO 02/02552	01/10/2002	PCT			X
	8.	WO 02/056912	07/25/2002	PCT			X

Continue on page ___

OTHER DOCUMENTS (Including Author, Title, Journal-Date, Page Number, Etc.)

	9.	Bargmann et al., "Oncogenic activation of the *neu*-encoded receptor protein by point mutation and deletion," *EMBO* **7(7)**:2043-2052 (1988).
	10.	Burris, "Dual kinase inhibition in the treatment of breast cancer: Initial experience with the EGFR/ERbB-2 inhibitor lapatinib," *The Oncologist 9 Suppl.* **3**:10-15 (2004).
	11.	Christianson et al., "NH_2-terminally truncated HER-2/neu protein: relationship with shedding of the extracellular domain and with prognostic factors in breast cancer," *Cancer Research* **58(22)**:5123-5129 (Nov. 1998).
	12.	Colomer et al. "Circulating HER2 extracellular domain and resistance to chemotherapy in advanced breast cancer," *Clin. Cancer Research* **6(6)**:2356-2362 (Jun. 2000).
	13.	DiFiore et al., "*erb*B2 is a potent oncogene when overexpressed in NIH/3T3 cells," *Science* **237**:178-182 (Jul. 1987).
	14.	Harris et al., "Comparison of methods of measuring *HER-2* in metastatic breast cancer patients treated with high-dose chemotherapy," *J. Clin. Oncol.* **19(6)**:1698-1706 (Mar. 2001).
	15.	Molina et al. "Trastuzumab (Herceptin), a humanized anti-HER2 receptor monoclonal antibody, inhibits basal and activated HER2 ectodomain cleavage in breast cancer cells," *Cancer Res.* **61(12)**:4744-4749 (Jun. 2001).
	16.	Molina et al., "NH_2-terminal truncated HER-2 protein but not full-length receptor is associated with nodal metastasis in human breast cancer," *Clin. Cancer Res.* **8(2)**:347-353 (Feb. 2002).
	17.	Rusnak et al., "The characterization of novel, dual ErbB-2/EGFR, tyrosine kinase inhibitors: potential therapy for cancer," *Cancer Res.* **61(19)**:7196-7203 (Oct. 2001).
	18.	Rusnak et al., "The effects of the novel, reversible epidermal growth factor receptor/ErbB-2 tyrosine kinase inhibitor, GW2016, on the growth of human normal and tumor-derived cell lines *in Vitro* and *in Vivo*," *Mol. Cancer Therap.* **1(2)**:85-94 (Dec. 2001).
	19.	Segatto et al., "Different structural alterations upregulate in vitro tyrosine kinase activity and transforming potency of the *erb*B-2 gene," *Mol. Cell. Biol.* **8(12)**:5570-5574 (Dec. 1988).
	20.	Xia et al., "Anti-tumor activity of GW572016: a dual tyrosine kinase inhibitor blocks EGF activation of EGFR/erbB2 and downstream Erk1/2 and AKT pathways," *Oncogene* **21(41)**:6255-6263 (Sep. 2002)
	21.	Xia, "Truncated ErbB2 receptor (p95 ErbB2) is regulated by heregulin through heterodimer formation with ErbB3 yet remains sensitive to the dual EGFR/ErbB2 kinase inhibitor GW572016,"*x* **23(3)**:646-653 (Jan. 2004).

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EXAMINER	DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.